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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,004	02/12/2001	Bassil I. Dahiyat	A-67229-6/RFT/RMS/RMK	1900

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,004

Applicant(s)

DAHIYAT ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,13,21-24 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12,13,21-24,33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Amendment filed 10/21/2005 is acknowledged. Claims 12,13,21-24,33-35 are pending.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12,13,21-24,33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12,33-35 are amended to recite further method steps. The following new rejections address amendments to claim 12 and are similarly applicable to the corresponding method steps in claims 33-35.

- A. Claim 12, step c): The term "favorably ranked" is not clear. The only step that yields the primary library is application of force field calculation, no other steps which would produce "favorably ranked" protein variants are addressed. Thus, it is not clear how else the variant proteins are ranked and what constitutes a "favorable" ranking.
- B. Claim 12, step d): The term "determining a criteria" is not clear: what particular criteria, and what are the method steps that result in "determining" this criteria?
- C. Claim 12, step e): It is not clear how residues are being "selected" from a plurality of positions of plurality of proteins.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12,13,21-24,33-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 12,33-35 introduce new matter as they use the phrases “primary variant proteins”, “favorably ranked”, “favorably ranked primary variant proteins”, “selecting amino acid residues from ... said favorably ranked primary variant proteins”. The above indicated subject matter is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 U.S.C. § 101/ 112-1

4. Claims 12,13,21-24,33-35 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Applicant submits that amendment to the claims to recite that the primary library be comprised of favorably ranked primary protein variants renders specific utility to the

invention as now claimed. In response, first the language “favorably ranked primary protein variants” is a new matter, and is not disclosed in the specification. Second, as it is not clear what constitutes “favorable ranking”, such amendment is not sufficient to provide specific utility to the method as claimed.

Further, whatever the preceding method steps are, step f) of claim 1 is directed to generation of yet another library, secondary library of protein variants, which are a combination of amino acid residues selected from protein variants of the first library. Thus, the instantly claimed method provides for generating a secondary library of as yet undetermined structure, function or biological significance which is obtained by a random combination of amino acid residues derived from a plurality of variant positions.

Note that specification, paragraph [0103], guides that

... in general, the variant positions and/or amino acid residues in the variant positions can be recombined in any number of ways to form a new library that exploits the sequence variations found in the primary library.

Thus, one can envision, that, for example, for a protein having 100 residues, and assuming that all 100 positions are considered to be “variant positions” and the residues are natural amino acids, the secondary library will be comprised of a random permutation of all 20 natural amino acid residues. Utility of such random library is not addressed neither in specification, nor in applicant’s response.

Until some actual and specific significance can be attributed to the secondary library or even the compounds present the library, an artisan would be required to perform additional experimentation in order to determine how to use the generated secondary library. Thus, there was no immediate “real world “ utility as of the filing date. Because any potential pharmacological or any other utility is not yet known and has not

yet been disclosed, the utility is not substantial because it is not currently available in any specific and practical form.

Therefore, the claimed method secondary library of as yet undefined structure generated from the claimed method does not have a specific and substantial or real-world utility well-established utility.

Claim Rejections - 35 USC § 102 and 103 .

5. Rejection of claims 12,13,21-24,33-35 over Lacroix et al are withdrawn in view of amendments to the claims.

Note, however, that the rejection will be re-applied once the new matter is removed from the claim language.

Double Patenting

6. Claims 12, 21-24, 33-35 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 of copending Application No. 09/927790 in view of Wang et al (Pub. Med ID 8862547; Protein Engineering, 9(6),479-484, 1996) or Ulrich et al (Proteins: Structure, Function, and Genetics, 27,367-384, 1997).

Applicant requests that the rejection is reevaluated once the claims of both applications are in condition for allowance.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'M. Borin', with a long horizontal stroke extending to the right.

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb
1/19/2006